MAY 16 2005

K050983

510(k) Summary

Submitter Information

International Technidyne Corporation
2656 Patton Rd.
Roseville, MN 55113
(800) 949-4762

Establishment Registration Number: 2183953

Contact: Nancy Ring
Date Prepared: 4/15/05

Device Information

Proprietary Name:	The IRMA TRUpoint™ Creatinine Control Kit
Common Name:	Creatinine Controls
Classification	(21 CFR 862.1660)
Classification Name:	Single Analyte Controls (Assayed and Unassayed)
Device Class:	I
Panel:	Chemistry
Product Code:	75JJX

Predicate Device

Substantial equivalence is claimed to the currently marketed Bionostics Inc. RNA 823 Controls (K943754) and Medical Analysis Systems' Moni-Trol H Controls (K030942).

Description of Device

The Creatinine Control Kit includes creatinine control materials at two levels for monitoring the IRMA analyzer performance at different points in the range of intended clinical utility. The control materials are packaged in capped luer lock syringes, each containing 1.5 ml of solution. The syringes are in turn packaged in pouches. Three (3) pouches/syringes for low level and three (3) pouches/syringes for high level are packaged in a box. The Cr control is an aqueous based solution of creatinine and sucrose. This control contains no human or biological materials.

Intended Use:

The IRMA TRUpoint™ Creatinine Control Kit (CR Control Kit) (074402) are assayed quality control materials and are intended to be used to perform Quality Control assays for Creatinine on the IRMA TRUpoint™ Blood Analysis System.

For *in vitro* Diagnostic Use.

Technological Comparison to Predicate

The IRMA TRUpoint™ Creatinine Control Kit is comprised of materials in the same form and aqueous matrix as the predicate device, Bionostics Inc. RNA 823 Controls (K943754), both perform quality control assays, and both are stored at 2°C - 8°C. The IRMA TRUpoint™ Creatinine Control contains only creatinine while the Bionostics RNA QC 823 is a multi-analyte control without creatinine.

The IRMA TRUpoint™ Creatinine Control Kit is comprised of materials in the same form as the predicate device, Medical Analysis Systems Moni-Trol H (K030942). Both are used to perform quality controls assays and contain creatinine. The IRMA TRUpoint™ Creatinine Control contains only creatinine and is aqueous based whereas the Medical Analysis Systems Moni-Trol-H is a multi-analyte control, human serum based, and is stored at -20°C until expiration date.

Substantial Equivalence Conclusion Summary

The IRMA TRUpoint™ Creatinine Control Kit is substantially equivalent to Bionostic's RNA QC 823 Blood gas, Electrolyte, Metabolite, and BUN control (K943754) and to Medical Analysis Systems Moni-Trol H (K030942) currently in commercial distribution. Both predicates have a similar intended use and are in a liquid form. The RNA QC823 control has a similar aqueous base and storage conditions. The Medical Analysis Systems Moni-Trol H is for the control of a similar analyte, creatinine.

The evaluations demonstrate that the IRMA TRUpoint™ Creatinine Control is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 16 2005

Ms. Nancy Ring
QA/RA Manager
International Technidyne Corp.
2656 Patton Road
Roseville, MN 55113

Re: k050983
Trade/Device Name: IRMA TRUpoint™ Creatinine Control Kit
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: April 15, 2005
Received: April 19, 2005

Dear Ms. Ring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050983

Device Name: IRMA TRUpoint™ Creatinine Control Kit

Indications for Use:

The IRMA TRUpoint™ Creatinine Control Kit is for use on the IRMA TRUpoint™ Blood Analysis System to perform Quality Control assays for Creatinine on the IRMA TRUpoint™ Blood Analysis System.

For *in vitro* Diagnostic Use Only

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K050983

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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